noted that MPEP 809.02(c)(B) requires examination of the non-elected species in the event of allowance of generic claim 1.

Claim 8 has been amended to delete certain language which is now not appropriate in view of the amendment to claim 1.

Claim 10 no longer includes phophastase catalyzed reactions and protease catalyzed reactions.

Specific support for amended claim 1 will be discussed in the comments concerning the rejection under 35 U.S.C. § 112, first paragraph.

The pending claims are claims 1, 3, and 5-20.

Claim 1 stands rejected under 35 U.S.C. §112, second paragraph as being indefinite for use of the term "distinct from". Amended claims 1 and 8 do not recite this term, therefore the rejection is now moot.

Claims 1, 3-10 and 19 stand rejected under 35 U.S.C. §102(e) as being anticipated by Kasila et al. (U.S. Patent No. 5,972,595).

Applicant's invention as defined in claim 1 requires that at least one of the reactant molecular species does not adsorb to the scintillating material and, therefore, does not result in scintillation. In marked contrast, the assay disclosed in Kasila et al. requires the reactant to be bound to the solid support (which could include a scintillator material therein). In Kasila et al., the bound reactant (i.e., substrate) is biochemically transformed resulting in a cleavage of a portion of the molecule, rendering the cleaved portion hydrophilic, which is then washed away. At all possible times during the Kasila assay, the reactant is bound to the scintillating material (if present).

Furthermore it is submitted that the Examiner's position in the Office Action regarding the cleaved molecule of Kasila is untenable. To hold that once a portion of a molecule is cleaved from the original molecule, that it is still somehow bound to the portion of the molecule from which it is cleaved, is specious at best, and lacks any support whatsoever in Kasila. In column 2, lines 17-19 of Kasila it is stated that the "labeled hydrophobic fragment will migrate into the aqueous phase, thereby no longer being associated with the solid support...". If the cleaved fragment migrates into the aqueous phase and is no longer associated with the solid support, how could it possibly be construed to still be bound to the portion of the molecule from which it is cleaved (which is still bound to the solid support)? The palpable answer is that it cannot.

Kasila's assay is fundamentally different from applicants' claimed method and there is nothing in Kasila that, even remotely, teaches or suggests applicants' invention.

Because Kasila does not teach or suggest applicants invention, it is manifest that an interference proceeding is inappropriate.

Claims 1, 3, 5-10 and 19 stand rejected under 35 U.S.C. §112, first paragraph, for allegedly introducing new matter. In discussing the rejection, the Office Action also cites MPEP § 714.02.

It is respectfully pointed out that reference to "new matter" and MPEP § 714.02 is inappropriate as such are concerned with amendments to the specification, not amendments to the claims. Applicants have not amended their specification. The issue under 35 U.S.C. § 112, first paragraph, is believed to be whether or not the specification provides sufficient written description to support the pending claims (see MPEP § 2163.01).

The Examiner objects to the phrase "reaction product of the chemical or biochemical transformation binds to the scintillating material". As understood by applicants, the Examiner's position is that there is insufficient support from the specific example cited in applicants' previous response (i.e. page 15, lines 13-16 of the specification) to support the "generic" language used. In applicants' amended claim 1 the phrase "and at least one of the reactants of said chemical or biochemical transformation does not bind to the scintillating material" has been added; applicants' understanding of the Examiner's basis for the § 112 rejection would appear to be applicable to this phrase as well. Applicants submit that this rejection is in error. As substantively pointed out in the Office Action, the test for sufficiency of support is whether the disclosure of the application reasonably conveys to the skilled artisan that the inventor had possession of the claimed subject matter. However, it is well settled that it is not necessary that the claimed subject matter be described in *ipsis verbis* to satisfy the written description requirement of 35 U.S.C. § 112 (see, for example, Purdue Pharma L.P. v. Faulding Inc.,56 USPQ2d 1481 (Fed. Cir. 2000)). Furthermore, explicit support is not required, inherent support is sufficient (see, for example, Standard Oil Co. v. Montedison, S.p.A., 206 USPQ 676 (D. Del. 1980), *aff'd*, 212 USPQ 327 (3d Cir. 1981), *cert. denied*, 456 U.S. 915 (1982)).

It is respectfully submitted that a skilled artisan clearly would understand that the specification as filed (in addition to the claims as filed) supports the method of applicants' claims, in particular, amended claim 1. Applicants' specification on pages 5-6 supports applicants' invention as claimed. More specifically, the first paragraph after "Disclosure of the Invention" on page 5 recites:

" The present invention provides a method for analyzing a sample which contains one or more molecular species, where at least one of the molecular species can stimulate scintillation of a scintillation material essentially only when adsorbed to the surface of the scintillating material. The scintillating material has a surface capable of adsorbing at least one of the molecular species via a general molecular property-based binding interaction. The molecular species capable of stimulating scintillation and adsorbed to the surface of the scintillating material are quantitated by measuring scintillation emitted by the scintillating material.

Furthermore, the last paragraph on page 5 recites:

"the aforementioned presence, absence or degree of general molecular property-based binding interaction with the scintillating material is due to a chemical or biochemical transformation of one of said molecular species into another of the molecular species".

As it is manifestly clear, such language covers the situation in applicants' claim 1 where the product of the transformation binds to the scintillation material and stimulates scintillation and where a reactant of the transformation does not bind and does not stimulate scintillation. Moreover, there is substantially more disclosure in the specification which supports the invention of applicants' claims. In addition to the very specific example cited in applicants' previous response on page 15, lines13-16 (i.e., the disclosure regarding D-Ala-D-Ala being incorporated into the Mur-pentapeptide), several other places on pages 13-19 and in the Examples that follow illustrate embodiments where the product binds to the scintillation material and stimulates scintillation and a reactant does not (where increased scintillation is correlated with reaction progression). Examples 3-5 demonstrate applicants' claimed method being used for other aspects of the Mur pathway. Other specific illustrations in the specification are the various reactions disclosed on pages 13-19 and in other Examples. More specifically, disclosed are a kinase reaction on pp. 17-18 and Example 10 (where the reactant not bound and not stimulating scintillation is (γ-^{32}P)-ATP; the product bound and stimulating scintillation is the phosphorylated peptide), a lipase reaction on page 18 and in Example 7 (where the reactant not bound and not stimulating scintillation is the tritiated lipid; the product bound and stimulating scintillation is the tritiated fatty acid), and a tRNA transferase reaction on page 19 (where the reactant not bound and not stimulating scintillation is the tritiated amino acid; the product bound and stimulating scintillation is the tritiated amino acid-tRNA product).

Clearly, applicant's specification provides sufficient support for their claimed invention to satisfy the requirements of 35 U.S.C. §112, first paragraph.

It is respectfully submitted that Applicant's specification and claims are in proper form. Applicants respectfully request that the rejection under 35 U.S.C. §112 and §102(e) be withdrawn and that pending claims 1, 3, and 5-20 be passed to allowance.

Respectfully submitted,

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Marked Up Version of Amended Claims
Pursuant to 37 C.F.R. § 1.121(c)(1)(ii)

1. (Four times amended) A method for analyzing a sample comprising:

e) providing a sample containing at least two molecular species, wherein at least one of the molecular species is capable of stimulating scintillation;

f) providing a scintillating material, wherein the surface of the scintillating material adsorbs at least one of the molecular species via a general molecular property-based binding interaction between the molecular species and the scintillating material, and where the scintillating material can be stimulated to scintillate above background by at least one of the adsorbed molecular species, but is not stimulated to scintillate above background by any molecular species which is not adsorbed**[**, where at least one of said molecular species has a presence of, absence of, or a degree of general molecular property-based binding interaction with the scintillating material distinct from the remainder of the molecular species**]**;

g) measuring the scintillation emitted by the scintillating material;

wherein the <u>adsorption of the molecular species to the scintillating material</u> **[**presence of, absence of, or the degree of general molecular property-based interaction with the scintillating material**]** is due to a chemical or biochemical transformation of one of said molecular species into another of said molecular species; and

h) determining the progress of or degree of completion of the molecular transformation;

wherein the reaction product of the chemical or biochemical transformation binds to the scintillating material<u>, and at least one of the reactants of said chemical or biochemical transformation does not bind to the scintillating material</u>.

8. (Three times amended) The method of claim 1, wherein at least one of the at least two molecular species provided is a substrate for an enzyme-catalyzed reaction or a series of enzyme-catalyzed reactions, another of the at least two molecular species is a product of the enzyme-catalyzed reaction or series of enzyme-catalyzed reactions **[**and has a presence of, absence of, or degree of general molecular property-based binding affinity for the scintillating material distinct from that of the substrate, and where the difference in general molecular propety-based binding affinty is a result of the enzyme-catalyzed reaction or series of enzyme-catalyzed reactions**]**.

10. (Twice amended) The method of claim 8, wherein the enzyme catalyzed reaction is selected from the group consisting of kinase catalyzed reactions, lipase catalyzed reactions, [phosphatase catalyzed reactions, protease catalyzed reactions,] and tRNA transferase catalyzed reactions.